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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/688,058

10/17/2003

Kathryn F. Sykes

MCRO:003US

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09/25/2006

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/688,058

Applicant(s)

SYKES ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-43, 48 and 88-91 is/are pending in the application.
- 4a) Of the above claim(s) 40-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48 and 88-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 40-43, 48 and 88-91 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' Response to Office Action, received 13 July 2006, is acknowledged. Claims 31-39, 44-47, and 49-51 have been canceled. Claims 40-43 and 48 have been amended. New claims 88-91 have been added.
2. Claims 40-43, 48, and 88-91 are pending. Claims 40-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
3. Claims 48 and 88-91 drawn solely to polypeptide compositions are pending and under consideration.

Rejections Moot/Withdrawn

4. The rejection of claims 45, 46, and 47 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.
5. The rejection of claims 31, 32, 34, and 44-47 under 35 U.S.C. 102(b) as being anticipated by Alliger et al (U.S. Pat. No. 5,582,829, Dec. 1996) is moot in light of the cancellation of the claims.
6. The rejection of claims 31, 32, 34, and 44-47 under 35 U.S.C. 102(b) as being anticipated by Bergstrom et al (U.S. Pat. No. 5,688,512, Nov. 1997) is moot in light of the cancellation of the claims.
7. The rejection of claims 31, 32, 34, and 44-47 under 35 U.S.C. 102(b) as being anticipated by Lobet et al (U.S. Pat. No. 6,113,914, Sept. 2000) is moot in light of the cancellation of the claims.
8. The rejection of claims 31, 32, 34, 44-47 and 49-51 under 35 U.S.C. 102(b) as being anticipated by Choi et al (WO98/59071, Dec. 1998) is moot in light of the cancellation of the claims.

Rejections Maintained

9. The rejection of claim 48 under 35 U.S.C. 102(b) as being anticipated by Choi et al (WO98/59071, Dec. 1998) is maintained for reasons of record.

Applicants argue that Choi et al does not anticipate the instant claims because the disclosure of Choi et al is not enable eliciting an immune response in animals. The Examiner has considered applicants' argument, but does not find it persuasive. The instant claims are drawn to a vaccine composition comprising ≥ 1 *Borrelia* antigen or fragments thereof, selected from a listing of SEQ ID Nos. Choi et al teach the claimed antigens or fragments thereof, as stated in the original rejection. In addition, Choi et al do teach how to utilize the antigens or fragments thereof in a vaccine composition, pages 37-41, and section 6(c), page 54.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 48 and 88-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 48 is drawn to a nonelected invention, i.e., "a vaccine composition comprising a first polynucleotide". Claims newly added claims 88-91 depend from claim 48, but do not clarify the invention.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Newly added claims 88-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Choi et al (WO98/59071, Dec. 1998).

The claims are drawn to a vaccine composition comprising at least one (claim 48 and 91), or at least two (claim 88) or at least three (claim 89) or at least four (claim 90) different *Borrelia* antigens, or fragments thereof.

Choi et al teach the claimed vaccine composition combinations by teaching a vaccine composition comprising at least one or more *B. burgdorferi* polypeptides selected from a group consisting of four different peptide constructs (claim 16) in a pharmaceutically acceptable carrier. One of the whole peptides from which the constructs are formed, listed in Table 1 (f810.aa; page 134), is identical to the instantly claimed SEQ ID NO:8, and comprises a fragment of instantly claimed SEQ ID NO:6. Another whole peptide from which the constructs are formed as taught by Choi et al (f229.aa; page 169) is 98.2% identical to the instantly claimed SEQ ID NO:12. In addition, Choi et al do teach how to utilize the antigens or fragments thereof in a vaccine composition, pages 37-41, and section 6(c), page 54.

Conclusion

14. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of

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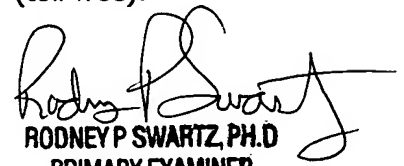
the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's acting supervisor, Albert M. Navarro, can be reached on (571)272-0861.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

September 16, 2006